

We claim:

1. An anti-infective medical device, comprising a polymeric matrix with an oxidant producing component within the matrix which is stable at least until the device is contacted by water.

2. The anti-infective medical device of claim 1 wherein the oxidant producing component produces an anti-infective oxidant selected from the group consisting of elemental iodine, hydrogen peroxide, superoxide, nitric oxide, hydroxy radical, hypohalites, haloamines, thiocyanogen, and hypothiocyanite.

3. The anti-infective medical device of claim 1 wherein the oxidant producing component is selected from the group consisting of an iodine-containing salt, percarbamide, perborate, sodium perborate monohydrate, sodium perborate tetrahydrate, sodium percarbonate, calcium peroxide, ammonium persulfate, benzoyl peroxide, cumyl hydroperoxide, 3-morpholinolinosydnonimine hydrochloride, substrate oxidoreductases, glucose oxidase, spermine, putrescine, benzylamine of diamine oxidase, S-nitroso-N-acetylpenicillamine, and N-(2-aminoethyl)-N-(2-hydroxy-nitrohydrazino)-1,2-ethylenediamine.

4. The anti-infective medical device of claim 1 wherein the oxidant producing component is stable until contacted by water and by an oxidizing agent which oxidizes the oxidant producing component.

5. The anti-infective medical device of claim 4 wherein the oxidant producing component is an iodide.

6. The anti-infective medical device of claim 5 wherein the iodide comprises solid particles dispersed within the polymeric matrix in a sufficient amount to provide anti-infective activity to the medical device.

7. The anti-infective medical device of claim 1 wherein the oxidant producing

component is stable until contacted by water and by a reducing agent which reduces the oxidant producing component.

8. The anti-infective medical device of claim 7 wherein the oxidant producing component is an iodate.

9. The anti-infective medical device of claim 1 wherein the oxidant producing component is stable until contacted by water and by protons.

10. The anti-infective medical device of claim 1 wherein the oxidant producing component is present in a sufficient amount to provide spermicidal activity to the medical device.

11. An anti-infective medical device, comprising a polymeric matrix with an elemental iodine producing component within the matrix which is stable at least until the device is contacted by water.

12. The anti-infective medical device of claim 11 wherein the iodine producing component is an iodide.

13. The anti-infective medical device of claim 12 wherein the polymeric matrix includes an oxidizing agent selected from the group consisting of anhydrous alkali iodine oxide salts, inorganic or organic peracids, and oxidase enzymes.

14. The anti-infective medical device of claim 12 wherein the iodine producing component is an iodate.

15. The anti-infective medical device of claim 11 wherein the polymeric matrix includes a proton producing agent.

16. The anti-infective medical device of claim 15 wherein the proton producing

agent is selected from the group consisting of iodine pentoxide, organic acid, inorganic acid, an anhydride, and an enzyme oxidase.

17. A medical device having anti-infective activity, comprising a polymeric material having an iodine-containing salt and an oxidizing agent within the polymeric material.

18. The medical device of claim 17 wherein the iodine-containing salt is an iodide selected from the group consisting of potassium iodide and sodium iodide.

19. The medical device of claim 18 wherein the polymeric material is a hydrophobic polymer selected from the group consisting of silicone elastomers, polyurea, polyurethane, ethylene vinyl acetate, polyvinylchloride, polyesters, polyamides, polycarbonate, polyethylene, polypropylene, polystyrene, polytetrafluoroethylene, poly(ethylenevinyl acetate).

20. The medical device of claim 19 wherein the iodide is provided at a concentration of about 0.01% to about 16% (by weight) of the polymeric material.

21. The medical device of claim 17 wherein the oxidizing agent is selected from the group consisting of anhydrous alkali iodine oxide salts, inorganic peracids, organic peracids, and substrate oxidase enzymes.

22. The medical device of claim 21 wherein the anhydrous alkali iodine oxide salts are selected from the group consisting of potassium iodate, sodium iodate, and iodine pentoxide.

23. The medical device of claim 21 wherein the inorganic or organic peracids are selected from the group consisting of perborates and organoperoxy acids.

24. The medical device of claim 21 wherein the inorganic peracids and organic peracids are provided at a concentration of from about 0.01% to about 16% by weight of the polymeric material, provided the inorganic or organic peracids are the only oxidizing agents

present in the polymeric material.

25. The medical device of claim 21 wherein the substrate oxidase enzyme is present at a concentration of from about 0.01% to about 2.5% by weight of the polymeric material, provided the substrate oxidase enzyme is the only oxidizing agent present in the polymeric material.

26. The medical device of claim 21 wherein the substrate oxidase enzyme is a H_2O_2 generating oxidase enzyme selected from the group consisting of glucose oxidase and diamine oxidase.

27. The medical device of claim 26 wherein the glucose oxidase has a specific activity in the range of 2,000 to 200,000 IU per gram of glucose oxidase, and the diamine oxidase has a specific activity in the range of 50 to 800 IU per gram of diamine oxidase.

28. The medical device of claim 19 including a peroxidase enzyme.

29. The medical device of claim 28 wherein the substrate oxidase enzyme is a glucose oxidase present at a concentration of at least 0.01% by weight of the polymeric material, and the peroxidase is present at a concentration of at least 0.01%, and the sum concentration of a combination of oxidase and peroxidase enzymes is within the range of about 0.01% to about 2.5% by weight of the polymeric material.

30. The medical device of claim 28 wherein the substrate oxidase is a diamine oxidase present at a concentration of at least 0.01% by weight of the polymeric material, and the peroxidase is present at a concentration of at least 0.01% by weight of the polymeric material, and the concentration of the enzymes is within the range of from about 0.01% to about 2.5% by weight of the polymeric material .

31. The medical device of claim 17 wherein the polymeric material is a hydrogel

selected from the group consisting of linear polyacrylates or cross-linked polyacrylates, hydroxyalkyl celluloses, polycarboxyalkyl celluloses, water soluble cellulose, polyethylene or vinyl alcohols, chitosan polymers, salts of alginic acid, starch, or combination thereof, the hydrogel containing the iodine-containing salt and oxidizing agent therein to form a hydrogel formulation

32. The medical device of claim 31 wherein the hydrogel is made up to not less than about 0.2% by weight in water, and not more than about 5% by weight in water.

33. The medical device of claim 31 wherein the hydrogel is about 2% by weight of the hydrogel formulation.

34. The medical device of claim 31 wherein the pH of the hydrogel formulation is from about pH 3.0 to about pH 6.5.

35. The medical device of claim 31 wherein the pH is about 4.0.

36. The medical device of claim 31 wherein the iodine-containing salt is an iodide having a concentration in the hydrogel formulation of about 0.1 mM to about 200 mM.

37. The medical device of claim 31 wherein the oxidizing agent is selected from the group consisting of an alkali oxide of iodine or a peracid, and is present in the hydrogel formulation at a concentration from about 0.1 mM to about 200 mM.

38. The medical device of claim 31 wherein the oxidizing agent is a H_2O_2 generating enzyme oxidase, and is present in the hydrogel formulation at a concentration from about 2 $\mu\text{g/ml}$ to about 500 $\mu\text{g/ml}$.

39. The medical device of claim 31 including a peroxidase enzyme present at a

concentration of from about 2 µg/ml to about 500 µg/ml and having a specific activity of about 250,000 to 330,000 IU per gram of peroxidase enzyme.

40. The medical device of claim 31 wherein the hydrogel is desiccated.

41. The medical device of claim 21 wherein the polymeric matrix includes a substrate which is oxidized by the substrate oxidase.

42. The medical device of claim 17 wherein the polymeric material includes a proton producing agent.

43. The medical device of claim 42 wherein the proton producing agent is selected from the group consisting of iodine pentoxide, an anhydride, an organic or inorganic acid, or an enzyme oxidase.

44. The medical device of claim 17 including a proton producing agent on a surface of the medical device.

45. The medical device of claim 17 wherein the polymeric material includes a desiccant.

46. The medical device of claim 45 wherein the desiccant is selected from the group consisting of a dry powder mixture of from about 1% to about 10% polyvinylpyrrolidone, calcium chloride, and calcium sulfate.

47. The medical device of claim 17 wherein the medical device is selected from the group consisting of catheters, guidewires, gloves, prostheses, implants, and contraceptive devices.

48. The medical device of claim 17 wherein the device comprises a sheet of the polymeric matrix having a thickness of about 0.1 mm to about 10 mm.

49. The medical device of claim 17 wherein the medical device is a circular member configured to be implanted in the vagina, or cervical region, having an outer diameter of about 3 cm to about 7 cm.

50. The medical device of claim 49 wherein the circular member has a thickness of about 0.5 cm to about 1.5 cm.

51. The medical device of claim 17 wherein the device has at least a layer of the polymeric material.

52. The medical device of claim 17 wherein the polymeric material is a coating on a surface of the medical device.

53. The medical device of claim 17 wherein the device comprises at least a first layer of the polymeric material and a second layer of the polymeric material, and the iodine-containing salt being in the first layer, and the oxidizing agent being in the second layer.

54. The medical device of claim 53 wherein the polymeric material is a hydrogel selected from the group consisting of linear polyacrylates or cross-linked polyacrylates, hydroxyalkyl celluloses, polycarboxyalkyl celluloses, water soluble cellulose, polyethylene or vinyl alcohols, chitosan polymers, salts of alginic acid, and starch.

55/ An anti-infective medical device, comprising

- a) a body formed of a polymeric material, having at least one reservoir chamber; and
- b) a solution having an oxidant producing compound within the reservoir.

56. The medical device of claim 55 wherein the oxidant producing compound is selected from the group consisting of an iodine-containing salt, percarbamide, perborate, sodium perborate monohydrate, sodium perborate tetrahydrate, sodium percarbonate, calcium peroxide, ammonium persulfate, benzoyl peroxide, cumyl hydroperoxide, 3-morpholinodisodnonimine hydrochloride, substrate oxidoreductases, glucose oxidase, spermine, putrescine, benzylamine of diamine oxidase, S-nitroso-N-acetylpenicillamine, and N-(2-aminoethyl)-N-(2-hydroxy-nitrohydrazino)-1,2-ethylenediamine.

57. The medical device of claim 55 wherein the anti-infective oxidant is selected from the group consisting of elemental iodine, hydrogen peroxide, superoxide, nitric oxide, hydroxy radical, hypohalites, haloamines, thiocyanogen, and hydrothiocyanite.

58. The medical device of claim 55 wherein the oxidant producing compound is an iodide and the solution includes an oxidizing agent selected from the group consisting of alkali iodine oxide salts, peracids, and H_2O_2 -generating enzyme oxidases.

59. The medical device of claim 58 wherein the solution includes a proton producing agent.

60. The medical device of claim 55 wherein the device is configured for vaginal implantation, and the oxidant producing component is present in a sufficient amount to provide spermicidal activity to the medical device.

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